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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

BEISNER, WILLIAM H

ART UNIT PAPER NUMBER

1744

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/070,343

Applicant(s)

SCHNELL ET AL.

Examiner

William H. Beisner

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1, 4-14, 16, 17 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al.(US 6,391,541) in view of Cheng et al.(US 6,071,394).

The reference of Petersen et al. discloses a cartridge (40) for conducting thermal cycling of fluids including a substantially planar and heat conducting wall (48); a light transparent wall (46) which is disposed substantially vertical to the heat conducting wall (48); a fluid inlet (41) for providing the cartridge with fluid; a fluid outlet (43) for draining fluid or gas from the cartridge; and a channel connecting the inlet and outlet defined by elements (50, 52 and 42) wherein the channel includes a protrusion defined by wall (59B) such that the channel between the inlet and outlet is longer than the shortest distance between the inlet and outlet and avoids bubbles in the measuring section (42) of the cartridge (See Figure 22 and column 13, line 56, to column 14, lines 5).

While the reference of Peterson et al. discloses an inlet (41) and outlet (43) communicated with channel (50, 52 and 42), the reference is silent as to the wall construction between the inlet and/or outlet and the channel (50, 52 and 42). Specifically, Claim 13 differs by reciting that the walls of the channel adjacent to the fluid inlet and the fluid outlet form an angle of 100-150 degrees.

The reference of Cheng et al. discloses a flow cell chamber (16) for a nucleic acid processing device that includes inlets and outlets (18b, 18c, 40b, 42b) and a channel (12) wherein the walls between the inlet and outlet and channel form an angle greater than 90 degrees and less than 180 degrees as shown in Figure 11b.

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the flow cell device of the primary reference of Petersen et al. with angled walls at the inlets and/or outlets of the flow cell for the known and expected result of providing

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an alternative means recognized in the art to introduce and remove liquid within a nucleic acid processing device that includes a flow cell while providing the advantages associated with the structure of the chamber of the reference of Petersen et al.

With respect to claim 14, the device includes two opposing heat-conducting walls (48).

With respect to claim 17, the light transparent wall (46) includes first and second sections (57A and 57B) for introducing and collecting light from the cartridge.

With respect to claims 12, 20 and 22, the cartridge can have a thickness of between 0.5 and 5mm (See column 11, line 48) and a depth (W or L) 1 or 1.4 mm (See column 11, lines 45-50).

With respect to claims 11 and 21, the cartridge has a quotient range of width to depth of 1 to 10 (See column 11, lines 45-50).

With respect to claim 1, the system includes cartridge (40) as discussed above with respect to claim 13 and also includes a thermocycling unit (147); a light source (216); a light detector (218) and a fluid providing unit (20).

With respect to claim 4, the light detector (218) is capable of detecting fluorescent light.

With respect to claim 5, the thermal cycling unit includes heat plates (190A and 190B).

With respect to claims 8 and 9, the transparent wall (46) includes first and second sections (57A and 57B) which are tilted.

With respect to claim 10, the thermal cycling unit includes heat plates (190A and 190B) which exert pressure on the cartridge when inserted between the plates (See Figure 23 and column 10, lines 32-45).

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With respect to claims 23 and 24, use of the device as disclosed by the reference of Petersen et al. meets the method steps of these claims since the reference of Petersen et al. is using the device to perform and optically monitor a PCR reaction in chamber (42).

Claims 6, 7 and 16, differ by reciting that the container is “wedge” shaped.

While figure 23 of the reference of Petersen et al. appears to disclose a wedge-shaped container, the written disclosure is silent to this fact. However, in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the container as a wedge shape so as to ensure contact between the sidewalls of the container and the heat plates of the heating device.

5. Claims 2, 3, 15, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Petersen et al.(US 6,391,541) in view of Cheng et al.(US 6,071,394) and Columbus et al.(EP 0 318 255).

The combination of the references of Petersen et al. and Cheng et al. has been discussed above.

Claims 2, 5, 15, 18 and 19 differ by reciting that the heat conducting walls are made of a metal foil.

The reference of Columbus et al. discloses that the use of aluminum foil wall (34) is conventional in the art for providing heat to a thermal cycling device (See column 7, line 54, to column 8, line 11).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ foil heating conducting walls in the system of the primary reference for the known and

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expected result of providing a high rate of thermal transfer to the PCR reagents within the processing chamber.

Response to Arguments

6. With respect to the rejection of claims 1-24 under 35 USC 102 and 103 over the reference of Petersen et al. alone or further in view of the reference Columbus et al., Applicants argue (See pages 6-8 of the response filed 12/20/05) that amended claims 1 and 13 define over the reference of Petersen et al. and the secondary reference of Columbus et al. because neither reference discloses the angles of the wall recited in the claims.

In response, while Applicants' amendments to the claims and associated arguments are persuasive to overcome the rejections of record. A new ground of rejection has been made over the combination of the reference of Petersen et al. with Cheng et al.(US 6,071,394) to address the newly recited claim limitations.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period


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will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys J. Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


William H. Beisner
Primary Examiner
Art Unit 1744

WHB